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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,820	09/20/2005	Norbert Heske		3682

7590  
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10/17/2007

EXAMINER
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STOUT, MICHAEL C

ART UNIT	PAPER NUMBER
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4123

MAIL DATE	DELIVERY MODE
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10/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/549,820

Applicant(s)

HESKE ET AL.

Examiner

Michael C. Stout

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 20 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11 October 2005.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This detailed action is in regards to US Patent Application 10/549820 filed 20 September 2005 and is a first action based on the merits of the application.

#### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "specimen removal space" referred to in claim 1 must be shown and labeled or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because a) the lines, numbers and letters are not uniform, clean and well defined (of a generally poor quality) in Figures 2-4 (37 CFR 1.84(I)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities:
4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading** (emphasis added). If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.

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(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification lacks a heading for each of the above sections (a)-(l). The headings should appear in uppercase, without underlining or bold type above their respective sections. Appropriate action is required.

5. The second paragraph on page 4 of the disclosure has an extra "," after the phrase "a vacuum created in the hollow needle;." Appropriate action is required.

### ***Claim Objections***

6. Claims 3 and 4 are objected to because of the following informalities:

Claims 3 and 4 contain the words [stopper] and [sic] respectively. These appear to be left from corrections. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the guide roller" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 4 has been interpreted as having "a guide roller."

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga US 5,718,237 in view of Teo US 7,156,836 B2.

Haaga teaches a coaxial cannula that can be used in tissue, in which for removing tissue are a biopsy needle unit (an inner tubular cannula 12 and a solid circular stylet 16, see Column 5 Lines 30-35) with specimen removal space (recess 66, see Figure 4) and a longitudinally movable specimen separating device that coaxially encloses the biopsy needle on the exterior wall (the inner cannula has a distal portion for cutting and capturing the specimen in the recess for removal from the site upon withdrawal of the needle from the patient, see Abstract and Figures 7-9). However Haaga fails to teach where the coaxial cannula has on its proximal end a sealing element that encloses the space between the interior wall of the coaxial cannula and the exterior wall of the specimen separating device, characterized in that the sealing element releases the air outlet when the needle unit is inserted and prevents air from entering after the needle unit has been positioned and a vacuum has been created in the biopsy needle interior space.

Teo teaches a coaxial cannula device wherein the coaxial cannula has on its proximal end a sealing element (one way valve between the inner cannula 14 and the

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outer cannula 10, see Column 5 Lines 57-60)) that encloses the space between the interior wall of the coaxial cannula and the exterior wall of the specimen separating device, characterized in that the sealing element releases the air outlet when the needle unit is inserted (one-way valve to prevent the ingress of a fluid (air) but allows it to escape, see Column 5 Lines 57-60) and prevents air from entering after the needle unit has been positioned and a vacuum has been created in the biopsy needle interior space.

Both Haaga and Teo teach coaxial cannula devices. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device taught by Haaga to include a one-way valve as taught by Teo in order to prevent the ingress of air, (see Teo Column 5 Line 59).

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga US 5,718,237 in view of Teo US 7,156,836 B2 as applied to claim 1 above, and further in view of Carrillo, JR. et al. US 2003/0088153.

Haaga/Teo teaches the coaxial cannula in accordance with claim 1 as set forth above wherein the one-way valve (seal sealing element) such that it allows air to egress when the internal pressure is high but when the internal pressure is lower the one-way valve creates a seal which prevents the ingress of air into the space between the inner and outer cannulas. However, Haag fails to teach the cannula characterized in that a hose-type sealing element is pushed over the proximal end of the coaxial cannula tube,



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the interior diameter of which is dimensioned so that it leaves open a slight gap between the sealing element and the biopsy needle unit.

Carrillo teaches an outer cannula wherein a hose-type sealing (valve 212 Figure 9b) element is placed at the proximal end of the outer cannula tube (see Figure 9b) for receiving an instrument, the interior diameter of which is dimensioned so that it leaves open a slight gap (there is a hole in the middle of the valve in Figure 9b).

Both Haaga/Teo and Carrillo teach cannula devices. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the valve taught by Carrillo for the valve in the device taught by Haaga/Teo in order to achieve the result of preventing the ingress of air.

The discussion of the elasticity in claim 2 discusses how a one-way valve would function in the apparatus disclosed and provides only desired functional operation of how the one-way valve would work subject.

14. Claims 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga/Teo/Carrillo as applied to claim 2 above, and further in view of Goldenberg US 6,033,369.

Haaga/Teo/Carrillo teach the coaxial cannula defined in claim 2 as set forth above further comprising a guide roller and stopper (Teo teaches a guide roller and stopper [a needle hub 17 that fits into the cannula hub 13], connected to the inner cannula see Column 3 5<sup>th</sup> Paragraph and Figure 17). Haaga/Teo/Carrillo fail to teach

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a stopper with sealing elements, which [stopper] is inserted into a counterpiece on the proximal end of the cap of the coaxial cannula such that the opening is closed shortly prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula.

Goldenberg teaches a stopper (cap 62, see Figure 1) with sealing elements (threads 64, Figure 1), which [stopper] is inserted into a counterpiece (handle 32 of the outer tube 14, Figure 1) on the proximal end (see Figure 1) of the cap of the coaxial cannula (needle 12) such that the opening is closed shortly prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula (also see Column 4 Last Paragraph).

Both Haaga/Teo/Carrillo and Goldenberg teach biopsy devices. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device taught by Haaga/Teo/Carrillo to include the stopper with sealing elements taught by Goldenberg in order to prevent the operator from inadvertently moving stylet (see Goldenberg Column 5 Lines 15-20).

15. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga/Teo as applied to claim 1 above, and further in view of Goldenberg US 6,033,369.

Haaga/Teo teaches the coaxial cannula defined in claim 2 as set forth above further comprising a guide roller and stopper (Teo teaches a guide roller and stopper [a needle hub 17 that fits into the cannula hub 13], connected to the inner cannula see Column 3 5<sup>th</sup> Paragraph and Figure 17). Haaga/Teo fail to teach using an intermediate

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piece between the distal end face of a guide roller with stopper and the proximal end face of the cap with counterpart, the intermediate piece has on its proximal side a counter coupling part as a type of interior bore into which the stopper of the guide roller with sealing elements is inserted and in that on the distal side the intermediate piece has a stopper with sealing elements [sic] (19), which [stopper] is inserted into the proximal-side counterpart of the cap of the coaxial cannula.

Goldenberg teaches a stopper (cap 62, see Figure 1) with sealing elements (threads 64, Figure 1), which [stopper] is inserted into a counterpart (handle 32 of the outer tube 14, Figure 1) on the proximal end (see Figure 1) of the cap of the coaxial cannula (needle 12) such that the opening is closed shortly prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula (also see Column 4 Last Paragraph). Goldenberg fails to teach an intermediate piece between the distal end face of a guide roller with stopper and the proximal end face of the cap. However, the insertion addition of an intermediate piece, which thereby creates a device requiring three components to perform the same function of the device requiring only two components taught by Goldenberg, represents the mere duplication of parts, thus using an intermediate piece in the stopper with sealing elements has no patentable significance unless new and unexpected results are produced. In re Harza, 124 USPQ 378 (CCPA 1960). Therefore the addition of an intermediate piece would have been obvious to one of ordinary skill in the art at the time of the invention because such is an obvious matter of design choice wherein no stated problems are being solved and no unexpected results are obtained over the prior art.

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Both Haaga/Teo and Goldenberg teach biopsy devices. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device taught by Haaga/Teo to include the stopper with sealing elements taught by Goldenberg in order to prevent the operator from inadvertently moving stylet (see Goldenberg Column 5 Lines 15-20).

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Form 892.

### ***Contact Info***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Stout whose telephone number is 571-270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCS

  
JOSEPH DEL SOLE  
SUPERVISORY PATENT EXAMINER  
10/15/07